

Serial No. 09/919,232
Response to Office Action

PATENT
Docket No.: US010394
Customer No. 000024737

REMARKS

By this amendment, claims 1 and 18 have been amended. Claims 2, 4, 9-11, 13-17 and 21 have been cancelled. Claims 1, 3, 5-8, 12, 18-20 and 22 remain in the application. This application has been carefully considered in connection with the Examiner's Action. Reconsideration, and allowance of the application, as amended, is respectfully requested.

Rejection under 35 U.S.C. § 103

Claim 1

Claim 1 recites an acoustic imaging system, comprising: a transducer including a two-dimensional transducer element matrix array encased by a protective cover and a transducer body, the protective cover having a non-uniform thickness and configured to mate with a protective cover mounting portion of the transducer body, the protective cover for being superposed above the two-dimensional transducer element matrix such that acoustic energy incident at the protective cover from the two-dimensional transducer element matrix is mechanically directed by the protective cover of the non-uniform thickness, wherein the protective cover further comprises an acoustic material for exhibiting an acoustic impedance corresponding to an acoustic impedance of a body to be imaged and further having a shape that includes a tissue-engagement surface and curved surfaces adjacent the tissue-engagement surface, the shape specified to provide an optimum contact with the body to be imaged, wherein the curved surfaces align the tissue-engagement surface in relation to an acoustic window defined by geometry-limited access points of the body to be imaged; and an image processing system coupled to the transducer and configured to provide a plurality of individualized excitation signals each being delayed by a predetermined delay with respect to each other according to a two-dimensional delay profile to control respective transducer elements of the plurality of transducer elements at different times for controlling lateral and elevation dimensions of the transmit aperture of the acoustic imaging system over

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time to compensate for the shape of the protective cover such that the two-dimensional transducer element matrix array generates and transmits acoustic energy through the protective cover over time according to the two-dimensional delay profile, wherein the image processing system electronically focuses transmitted acoustic energy at a target position within the body to be imaged through the protective cover as a function of (i) a position of each element of the two-dimensional transducer element array matrix, (ii) a thickness of the protective cover over a corresponding transducer element, and (iii) the target position within the body to be imaged, thereby electronically compensating for the focusing characteristics of the protective cover as a function of non-uniform acoustic delays introduced by the protective cover.

Claim 18

Claim 18 recites a method for acoustically imaging a patient, comprising the steps of: providing a transducer having a two-dimensional transducer element matrix array encased by a protective cover and a transducer body, the protective cover having a non-uniform thickness and configured to mate with a protective cover mounting portion of the transducer body, the protective cover for being superposed above the two-dimensional transducer element matrix such that acoustic energy transmitted from the protective cover and into the body is mechanically directed by the protective cover of the non-uniform thickness, wherein the two-dimensional transducer element matrix array and the protective cover are shaped to reduce patient discomfort, wherein the protective cover further comprises an acoustic material for exhibiting an acoustic impedance corresponding to an acoustic impedance of a body to be imaged and further having a shape that includes a tissue-engagement surface and curved surfaces adjacent the tissue-engagement surface, the shape specified to provide an optimum contact with the body to be imaged, wherein the curved surfaces align the tissue-engagement surface in relation to an acoustic window defined by geometry-limited access points of the body to be imaged; generating a plurality of time delayed transmit signals each for separately controlling a respective transducer element of the two-

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dimensional transducer element matrix array to electronically focus acoustic transmit waves that traverse through the protective cover, the plurality of time delayed transmit signals each being delayed by a predetermined delay with respect to each other according to a two-dimensional delay profile to control respective transducer elements of the plurality of transducer elements at different times for controlling lateral and elevation dimensions of a transmit aperture over time to compensate for the shape of the protective cover such that the two-dimensional transducer element matrix array generates and transmits acoustic energy through the protective cover over time according to the two-dimensional delay profile; and receiving a plurality of time delayed response echoes at the separately controllable individual transducer elements of the two-dimensional transducer element matrix array to electronically focus acoustic receive echoes that traverse the protective cover, wherein the image processing system electronically focuses transmitted acoustic energy at a target position within the body to be imaged through the protective cover as a function of (i) a position of each element of the two-dimensional transducer element array matrix, (ii) a thickness of the protective cover over a corresponding transducer element, and (iii) the target position within the body to be imaged, thereby electronically compensating for the focusing characteristics of the protective cover as a function of non-uniform acoustic delays introduced by the protective cover.

Claims 1, 4-9, 11, 12, and 18-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Iinuma (US 4217516) in view of Shimazaki (US 5083568). With respect to claims 4, 9, 11 and 21, the same have been canceled, thus rendering the rejection thereof moot. With respect to claim 1, applicant traverses this rejection on the grounds that these references are defective in establishing a prima facie case of obviousness.

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a

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prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...

It is submitted that, in the present case, a prima facie case of obviousness has not been factually supported for the at least the following, mutually exclusive, reasons.

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

The linuma and Shimazaki patents cannot be applied to reject claim 1 under 35 U.S.C. § 103 which provides that:

A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains ... (Emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. Neither linuma nor Shimazaki teaches a protective cover having a shape that includes a tissue-engagement surface and curved surfaces adjacent the tissue-engagement surface, the shape specified to provide an optimum contact with the body to be imaged, wherein the curved surfaces align the tissue-engagement surface in relation to an acoustic window defined by geometry-limited access points of the body to be imaged as is claimed in claim 1. Neither does linuma nor Shimazaki teach a plurality of individualized excitation signals each being delayed by a predetermined delay with respect to each other according to a two-dimensional delay profile ... for controlling lateral and elevation dimensions of the transmit aperture of the acoustic imaging system over time ... such that the two-dimensional transducer element matrix array generates and transmits acoustic energy through the protective cover over time according to the two-dimensional delay profile, wherein the image processing system electronically focuses ... through the protective cover as a function of (i) a position of each element of the two-dimensional transducer element array matrix, (ii) a thickness of the protective cover over a corresponding transducer element,

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and (iii) the target position within the body to be imaged, all as is claimed in claim 1.

In contrast, linuma teaches use of a single row of piezoelectric transducer elements, but does not teach use of a two-dimensional matrix of piezoelectric elements. In addition, Shimazaki teaches an acoustic lens 14 having a construction of a sub-lens 14a that is super-imposed on a sub-lens 14b. Shimazaki further teaches wherein sub-lens 14a forms a focal point Fa that serves to cover signal electrodes 13a and wherein sub-lens 14b forming a focal point Fb that serves to cover signal electrodes 13a, 13b1, and 13b2 (See Shimazaki at Column 1, lines 61-65). Shimazaki however does not teach or suggest, for all elements of a two-dimensional transducer element array matrix, the use of individualized excitation signals *according to a two-dimensional delay profile* for controlling both lateral and elevation dimensions *according to the two-dimensional delay profile*. Instead, Shimazaki teaches changing a combination of the arrays associated with transmission and/or receiving of the ultrasound waves depending on a depth of an object for observation (See Shimazaki Abstract).

Therefore, it is impossible to render the subject matter of claim 1 as a whole obvious, and the explicit terms of the statute cannot be met.

Thus, for this mutually exclusive reason, the examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. §103 should be withdrawn.

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2. The Combination of References is Improper

Assuming, arguendo, that the above argument for non-obviousness does not apply (which is clearly not the case based on the above), there is still another, mutually exclusive, and compelling reason why the linuma and Shimazaki patents cannot be applied to reject claim 1 under 35 U.S.C. § 103.

§ 2142 of the MPEP also provides:

...the examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made.....The examiner must put aside knowledge of the applicant's disclosure, refrain from using hindsight, and consider the subject matter claimed 'as a whole'.

Here, neither linuma et al. nor Shimazaki et al. teaches, or even suggests, the desirability of the combination since neither teaches the specific combination that includes a two-dimensional transducer element array and a plurality of individualized excitation signals each being delayed by a predetermined delay with respect to each other according to a two-dimensional delay profile ... for controlling lateral and elevation dimensions of the transmit aperture of the acoustic imaging system ... such that the two-dimensional transducer element matrix array generates and transmits acoustic energy through the protective cover over time according to the two-dimensional delay profile, as specified above and as claimed in claim 1.

Thus, it is clear that neither patent provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

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In this context, the MPEP further provides at § 2143.01:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

In the above context, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In the present case it is clear that the combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 1. Therefore, for this mutually exclusive reason, the examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met, and the rejection under 35 U.S.C. §103 should be withdrawn. Dependent claims 3, 5-8 and 12 depend from and further limit allowable independent claim 1 and therefore are allowable as well. Claim 18 is believed allowable for similar reasons as for allowability of claim 1. Dependent claims 19-20 and 22 depend from and further limit allowable independent claim 18 and therefore are allowable as well.

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Conclusion

It is clear from all of the foregoing that independent claims 1 and 18 are in condition for allowance. Dependent claims (3, 5-8 and 12) and (19-20 and 22) depend from and further limit independent claims 1 and 18, respectively, and therefore are allowable as well.

The amendments herein are fully supported by the original specification and drawing, therefore, no new matter is introduced. For example, support for the amendments can be found in the specification at least on page 13, lines 15-21; page 14, line 20; page 15, lines 3-6, 19, and 24-29; page 16, line 2, 29+; page 17, line 1, 8-9, and 14-19; page 18, lines 25-29; page 19, lines 13-17; page 20 line 1-2, 17-20; page 21, line 24, 31-32; and page 22, lines 15-16, and 20-25.

An early formal notice of allowance of claims 1, 3, 5-8, 12, 18-20 and 22 is requested.

Respectfully submitted,

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